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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,726	09/12/2001	Kenneth R. Korzekwa	CAMIP003	8838

22434 7590 09/30/2003

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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/954,726

### Applicant(s)

KORZEKWA ET AL.

### Examiner

Cheyne D Ly

### Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

**Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, drawn to a computer implemented method of predicting the relative reaction velocities of a first reaction pathway of a substrate in the presences of a cytochrome P450 enzyme to form a product, classified in class 702, subclasses 19 and 27.
  - II. Claims 7-11, drawn to a method of developing a model for predicting the rate at which a substrate is metabolized by a cytochrome P450 enzyme, classified in class 702, subclasses 19 and 27.
  - III. Claims 12-18, drawn to a method of determining the relative contribution of the second pathway, classified in class 435, subclasses 4, 7.1, and 183.
  - IV. Claims 19-25, drawn to a method of generating a model of substrate metabolism using the rate or amount of water formation for a substrate molecule in cytochrome P450 catalyzed reaction, classified in class 702, subclasses 19 and 27.
  - V. Claims 26-32, drawn to a method for calculating the rate or amount of consumption of peroxide formation for a substrate molecule in a cytochrome P450 catalyzed reaction, classified in class 435, subclasses 4, 7.1, and 183.
  - VI. Claims 33-36, drawn to a method for modeling reaction rates of cytochrome P450 metabolism for substrate molecules, classified in class 435, subclasses 4, 7.1, and 183.

- VII. Claims 37 and 38, drawn to a method of modeling absolute rates of cytochrome P450 metabolism for substrate molecules, classified in class 435, subclasses 4, 7.1, and 183.
- VIII. Claims 39-48, drawn to a computer program and method of predicting the relative reaction velocities of a first reaction pathway, classified in class 702, subclasses 19 and 27.

2. The inventions of Groups I-VIII are distinct inventions because they are directed to different methods regarding the critical limitations therein. For Group I, the critical limitation is a computer implemented method of predicting the relative reaction velocities of a first reaction pathway of a substrate in the presences of a cytochrome P450 enzyme to form a product. For Group II, the critical limitation is a method of developing a model for predicting the rate at which a substrate is metabolized by a cytochrome P450 enzyme. For Group III, the critical limitation is a method of determining the relative contribution of the second pathway. For Group IV, the critical limitation is a method of determining the relative contribution of the second pathway. For Group V, the critical limitation is a method for calculating the rate or amount of consumption of peroxide formation for a substrate molecule in a cytochrome P450 catalyzed reaction. For Group VI, the critical limitation is a method for modeling reaction rates of cytochrome P450 metabolism for substrate molecules. For Group VII, the critical limitation is a method of modeling absolute rates of cytochrome P450 metabolism for substrate molecules. For Group VIII, the critical limitation is a computer program and method of predicting the relative reaction velocities of a first reaction pathway. The completely distinct critical limitation of each

Group supports the undue search burden if they were examined together. Additionally, each method of use have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

9. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
9/13/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER